In the United States Court of Federal Claims

No. 06-725V
Filed: June 30, 2015[1]

ESFANDIAR SANTINI and LAURIE OMIDVAR, legal representatives of a minor child, AYDIEN CLIFF OMIDVAR, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SEVICES, Respondent.	National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa; Burden of proof, 42 U.S.C. § 300aa-13; Causation, 42 U.S.C. § 300aa-11(c)(1)(C)(ii); Review of Special Master's Decision, 42 U.S.C. § 300aa-12; Severity requirement, 42 U.S.C. § 300aa-11(c)(1)(D)(i); Significant Aggravation, 42 U.S.C. § 300aa-33.

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MEMORANDUM OPINION AND ORDER

BRADEN, *Judge*.

I. RELEVANT FACTUAL BACKGROUND.[2]

On July 6, 2003, Aydien Omidvar ("Aydien") was born to Laurie Omidvar and Esfandiar Santini ("Petitioners"). *See Santini v. Sec'y of Health & Human Servs.* No. 06-725, 2014 WL 7891507, at *5 (Fed. Cl. Spec. Mstr. Dec. 15, 2014) ("*Santini*").

[1] Pursuant to Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims ("VRCFC"), this Memorandum Opinion And Final Order was filed under seal on May 29, 2015 and "held for 14 days to afford each party the opportunity to object to the public disclosure of any information furnished by that party." VRCFC 18(b).

[2] The relevant facts discussed herein were derived from: the Special Master's decision, *Santini v. Sec'y of Health & Human Servs.*, No. 06-725, 2014 WL 7891507 (Fed. Cl. Spec. Mstr. Dec. 15, 2014) ("*Santini*"); Petitioners' January 9, 2015 Memorandum Of Objections ("Pet.

On September 8, 2003, Aydien was examined by his pediatrician and received a diphtheria, tetanus toxoids, and acellular pertussis vaccine ("DTaP"), without complication. *Id.* at *6.

On November 7, 2003, when Aydien was four months old, he received a second DTaP vaccination. *Id.* Prior to receiving the second dose of this vaccine, Aydien presented as a healthy baby. *Id.* Approximately ten hours after the vaccination, he experienced two seizures, each lasting about two minutes. *Id.* When a third seizure occurred on the same day, his parents called 911. *Id.* On arrival of Emergency Medical Services ("EMS"), Aydien's temperature was recorded as 100.8 degrees. *Id.* Thereafter, Aydien was transported to a local hospital, when EMS personnel observed continuous seizure activity for thirty minutes. *Id.* Two doses of valium were administered to stop the seizures. *Id.* Later that same day, Aydien was transported by air ambulance to San Diego Children's Hospital, where he remained for two days. *Id.* The admitting doctor recorded that "[t]he etiology of seizures is suspicious for adverse side effect of immunization, despite receiving 2-month immunizations without complications. Other possibilities include infection." *Id.* Tests on Aydien's blood, urine, and cultures revealed normal results. *Id.* On November 9, 2003, Aydien was discharged with a diagnosis of seizures due to DTaP immunization. *Id.*

On December 3, 13, and 19, 2003, Aydien suffered other seizures. *Id.* The last two seizures required Aydien to be admitted to San Diego Children's Hospital. *Id.* A December 15, 2003 Magnetic Resonance Imaging ("MRI") scan, however, revealed no noteworthy abnormalities. *Id.*

On May 10, 2004, Dr. Boosara Ratanawongsa, a neurologist at San Diego Children's Hospital, examined Aydien. *Id.* Dr. Ratanawongsa's diagnosis was that Aydien had epilepsy, but was otherwise "developmentally appropriate." *Id.* Although Aydien experienced other seizures during the next ten months, he made developmental progress. *Id.* at *7.

On March 14, 2005, Aydien had an electroencephalogram ("EEG") that showed "abundant interictal epileptiform discharges," and was diagnosed with "gross developmental delay." *Id.* Anti-seizure medication and the placement of a vagus nerve stimulator failed to control Aydien's seizures. *Id.*

II. PROCEDURAL HISTORY.

A. Proceedings Before The Special Master.

On October 20, 2006, Aydien's parents filed a *pro se* Petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1−34 ("the Vaccine Act"), alleging an "on-Table" claim, pursuant to 42 U.S.C. § 300aa-14.[3] *See Santini* at *7. The Government countered that Aydien did not suffer an "on-Table" injury, because he did not experience a decreased level of consciousness for twenty-four hours after receiving his first vaccination. *Id.* The Government also noted that the

Mot."); Petitioners' January 12, 2015 Addendum To Memorandum Of Objections ("Pet. Add. Mot."); and the Government's February 9, 2015 Response ("Gov't Resp.").

[3] 42 U.S.C. § 300aa-14 provides a table listing certain vaccines presumed to cause adverse physical effects. This section also contains definitions of different medical symptoms and conditions.

vaccine administered on November 7, 2003 was the acelullar form, DTaP, further indicating that Petitioners' claim was not on-Table. *Id.*

On February 26, 2007, the Government submitted an expert report from Dr. Max Wiznitzer,[4] a pediatric neurologist, concluding that Aydien's presentation was consistent with "severe myoclonic encephalopathy of infancy (SMEI or Dravet's syndrome)." *Id.* On October 2007, Petitioners agreed that Aydien would undergo genetic testing. *Id.*

On February 6, 2008, the Government filed the results of Aydien's genetic testing with the Special Master. *Id.* at *8. On February 28, 2008, Dr. Wiznitzer submitted a letter to the Special Master reporting that Aydien had a genetic mutation that was "consistent with a symptomatic mutation causally related to his clinical diagnosis of [SMEI]." *Id.*

On April 7, 2008, the Government also filed an expert report from Dr. Gerald Raymond[5] that concluded:

> Aydien Omidvar is a child who has Severe Myoclonic Epilepsy of Infancy ("SMEI") or Dravet syndrome secondary to a mutation in his SCN1A gene.[6] This

[4] Dr. Wiznitzer graduated from the Medical School at Northwestern University in 1977 and completed a pediatrics residency at Cincinnati Children's Hospital in 1980. *See Santini* at *2. He also completed a pediatrics fellowship at the Cincinnati Center for Developmental Disorders and a child neurology fellowship at the University of Pennsylvania Children's Hospital in Philadelphia in 1984. *Id.* Dr. Wiznitzer is board-certified in pediatrics and neurology with special qualification in child neurology and neurodevelopmental disabilities. *Id.* at *3. As a child neurologist, Dr. Wiznitzer is responsible for the outpatient practice at Rainbow Babies & Children's Hospital. *Id.*

[5] Dr. Raymond graduated from the Medical School at the University of Connecticut in 1984. *See Santini* at *2. He completed a residency in pediatrics at Johns Hopkins University in 1984 and studied child neurology at Massachusetts General Hospital from 1986–89. *Id.* Dr. Raymond is board-certified in clinical genetics and neurology, with a special qualification in child neurology, and Professor of Neurology and Director of Pediatric Neurology at the University of Minnesota. *Id.*

[6] The SCN1A gene is primarily responsible for creating $Na_v1.1$, a type of sodium channel. *See Santini* at *4. Sodium channels are parts of cells incorporated into a variety of organs. *Id.* They regulate electrical excitability that, in turn, determines the permeability of a cell's plasma membrane to sodium ions. *Id.* Prior to two or three months of age, $Na_v1.3$ is the sodium channel primarily responsible for maintaining balance in an infant's brain. *Id.* When a child reaches two to three months of age, the $Na_v1.1$ sodium channel helps to maintain balance instead. *Id.* An imbalance can lead to seizures, and in cases of severe and sustained seizures, a condition known as Dravet Syndrome may develop. *Id.*

Dravet Syndrome typically presents as an onset of clonic or hemi-clonic seizures in infants between four and eight months of age. *Id.* By age two or three, the child also may experience myoclonic seizures, absence seizures, and complex partial seizures. *Id.* Notably, the initial

> is the sole cause of his epilepsy syndrome including his subsequent developmental delay. It was not caused []or exacerbated by any of the immunizations that he received.

Id.

In October 2007, both of Aydien's parents underwent genetic testing to determine whether Aydien could have inherited the mutation from one of his parents' genes. *Id.* at *7. On December 11, 2008, Petitioners filed the results of their genetic tests: Aydien's mutation was not inherited, but arose *de novo*. *Id.*

On September 21, 2009, Petitioners requested a stay because of two cases pending before the United States Court of Appeals for the Federal Circuit: *Stone v. Secretary of Health & Human Services*, No. 04-1041V, 2010 WL 1848220 (Fed. Cl. Spec. Mstr. Apr. 15, 2010) and *Hammitt v. Secretary of Health & Human Services*, No. 07-170V, 2010 WL 3735705 (Fed. Cl. Spec. Mstr. Aug. 31, 2010). Both cases concerned the same vaccine and same genetic mutation that Aydien experienced, and the Special Master in those cases relied on the same expert who testified in Aydien's case, Dr. Raymond. *Santini* at *8. These two cases were consolidated on appeal. *See Stone v. Sec'y of Health & Human Servs*., 676 F.3d 1373 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 2022 (2013). In that case, the petitioners challenged the Special Master's finding that the SCN1A mutation was the sole cause of petitioners' injury. *Id*. at 1379. On April 26, 2012, the United States Court of Appeals for the Federal Circuit held that the Special Master's finding that the SCN1A mutation caused SMEI was not arbitrary or capricious, instructing that: "To prove causation, a petitioner must show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Id.* (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

Applying that standard, our appellate court concluded:

> Because the special master determined that the gene mutation was the sole cause of the children's SMEI, he did not engage in a superseding cause analysis, nor did he need to. The "superseding cause" analysis presupposes that the first factor was causally related to the injury; the analysis seeks to determine whether that causal relationship should be considered to have been superseded by subsequent events. That analysis has no role to play where, as here, the initial factor is found to have no causal relationship to the ultimate injury.

Id. at 1381.

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development in infants that develop Dravet Syndrome is normal, but by the time a child becomes a toddler, his or her development is adversely affected. *Id.* Dravet Syndrome is often diagnosed as generalized epilepsy with febrile seizures ("GEFS"); severe myoclonic epilepsy – borderline ("SMEB"); and SMEI. *Id.* Aydien's mutation was located at codon 1756 and resulted in his SCN1A gene producing the amino acid tyrosine, instead of the typical amino acid cysteine. *Id.* at *5.

On January 4, 2013, Petitioners filed an expert report by Dr. Jean-Ronel Corbier.[7] *Santini* at *9. Instead, "[d]ue to the underlying SCN1A mutation, DTaP caused new onset of prolonged seizures that made a significant contribution and was a catalyst for the development of Aydien's epilepsy and Dravet Syndrome." *Id.* (internal alteration omitted).

On March 22, 2013, the Government filed expert reports from Dr. Wiznitzer and Dr. Raymond challenging the opinions of Dr. Corbier. *Id.* at *10.

On June 5−6, 2013, this case was joined with *Barclay v. Secretary of Health & Human Services*, No. 07-605, and trial of both cases took place at the Mecklenburg County Courthouse in Charlotte, North Carolina, during which Dr. Corbier, Dr. Wiznitzer, and Dr. Raymond testified. 6/5/13 TR 11−219, 6/6/13 TR 482−543 (Corbier); 6/5/13 TR 220−273, 6/6/13 TR 277−334 (Raymond); 6/6/13 TR 335−481 (Wiznitzer). The parties stipulated that all matters in the record concerning *Barclay* were admissible in Aydien's case and vice versa. *See Santini* at *10.

On November 22, 2013, the Government filed a Post-Hearing Brief. On December 9, 2013, Petitioners filed a Post-Hearing Brief.

On December 15, 2014, the Special Master denied Petitioners' claim for compensation, because,

> Dr. Corbier was not persuasive in his opinion that vaccinations affected Aydien's outcome. The flip side of this coin is that Dr. Raymond and Dr. Wiznitzer were persuasive in opining that the SCN1A mutation was the sole cause. Consequently, [Petitioners] have failed to establish the first prong of *Althen* [*v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005)] and the [Government] has established an alternative factor.

Id. at *18.

The Special Master also concluded that:

> [T]he evidence overwhelmingly demonstrated that Aydien would be the same even if he did not receive the vaccine. The vaccination did not affect *or contribute* to his developmental delay. [Petitioners] have failed to meet their burden of establishing, by preponderant evidence, that he suffered an injury for more than six months.

[7] In 1995, Dr. Corbier graduated from Medical School at Michigan State University. *See Santini* at *2. He completed his residency at Michigan State University in 1997 and then completed a neurology fellowship training at Cincinnati Children's Hospital and the University of Cincinnati in 2000. *Id.* Dr. Corbier is board-certified in neurology with a special qualification in child neurology. *Id.* He currently is a full-time general pediatric neurologist in Concord, North Carolina. *Id.*

Id. at *20 (emphasis added).[8]

B. Proceedings Before The United States Court Of Federal Claims.

On January 9, 2015, Petitioners filed a Motion For Review And Memorandum Of Objections in the United States Court of Federal Claims ("Pet. Mot."). On January 12, 2015, Petitioners filed an Addendum To Memorandum Of Objections ("Pet. Add. Mot.").

On February 9, 2015, the Government filed a Response ("Gov't Resp."). On February 25, 2015, Petitioners requested oral argument.

On May 7, 2015, the court held oral argument in Washington, D.C. 5/7/15 TR 1–45.

III. DISCUSSION.

A. Jurisdiction.

The United States Court of Federal Claims has jurisdiction to review the Special Master's decision in vaccine cases. 42 U.S.C. §§ 300aa-12(e)(1)−(2) ("Upon issuance of the [S]pecial [M]aster's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. . . . Upon the filing of a motion . . . the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings[.]"). In this case, Petitioners filed a Motion For Review and Addendum To Motion For Review on January 9, 2015. Because this was within thirty days from the issuance of the Special Master's decision of December 15, 2014, the court has jurisdiction to adjudicate Petitioners' Motion.

B. Standard Of Review.

The Vaccine Act authorizes the United States Court of Federal Claims to set aside a Special Master's findings of fact or conclusions of law only if it determines they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 42 U.S.C. § 300aa-12(e)(2)(B); *see also Paluck v. Sec'y of Health & Human Servs.*, No. 2014-5080, 2015 WL 2403354, at *4 (Fed. Cir. May 20, 2015) (affirming that the United States Court of Federal Claims reviews "legal determinations without deference," but reviews "findings of fact under the arbitrary and capricious standard").

C. Petitioners' Motion For Review.

Petitioners' January 9, 2015 Motion For Review posits four reasons why the Special Master's decision failed to comply with 42 U.S.C. §300aa-12(e)(1)–(2). First, the Vaccine Act requires only an "inquiry into what caused the actual, acute change which occurred after

[8] By this time, Aydien continued to experience approximately four seizures per week and to lose consciousness. *Id.* at *7. His gait was unsteady, and he could speak only approximately fifty words. *Id.*

[Aydien's] November 7, 2003 vaccinations[,] rather than what caused a hypothetical difference in his ultimate outcome." Pet. Mot. at 11.

Second, the Special Master articulated, but failed to apply, the "clear legal framework" of the six-step causation analysis in a "significant aggravation" case adopted by the United States Court of Appeals for the Federal Circuit in *W.C. v. Secretary of Health & Human Services*, 704 F.3d 1352, 1357 (Fed. Cir. 2013). Pet. Mot. at 12−13. Instead, the Special Master's decision in this case was based on whether "the November 7, 2003 vaccine affected Aydien's outcome." Pet. Mot. at 14 (internal quotation marks omitted).

Third, "[t]he [S]pecial [M]aster should have determined whether the [Government] had satisfied the *Althen* standard for causation. He did not. The [S]pecial [M]aster substituted a different analysis—his analysis of whether Aydien Omidvar's vaccination had affected his ultimate outcome—for the analysis required by the Federal Circuit." Pet. Mot. at 17.

Fourth, the Special Master failed to consider an article entitled, "Novel SNC1A mutation in Indonesian patients with severe myoclonic epilepsy in infancy," 52 PEDIATRICS INT'L 234−39 (2010). Pet. Mot. at 20. In that case study, although a DTP vaccination caused the onset of seizures at the age of three months, a child with a mutation at the same codon position as Aydien (codon 1756) suffered "a milder disorder than Aydien Omidvar's. . . described as suffering Borderline Severe Myoclonic Epilepsy in Infancy (SMEB) and developmentally normal." Pet. Mot. at 20. Likewise, the Special Master failed to consider a second article of rodent studies to support a finding that mutations of the SCN1A gene do not necessarily result in Dravet Syndrome, 41 NEUROBIOLOGY OF DISEASE 261–69 (2011). Pet. Mot. at 21. Both of these deficiencies evidence that the Specials Master's December 15, 2014 Decision was arbitrary and capricious.

In addition, Petitioners' January 12, 2015 Addendum argues that the Special Master's interpretation of "severity," pursuant to 42 U.S.C. § 300aa-11(c)(1)(D)(i), was not in accordance with law, because where there is a significant aggravation of a pre-existing condition, the law requires only that "'the change for the worse' in the petitioner's preexisting condition persists for more than six months." Pet. Add. Mot. at 1–2. Here, "[t]he vaccine related change for the worse in Aydien Omidvar's condition was the change from a child who did not have seizures to a child who had frequent seizures . . . [that have] persisted for more than eleven years." Pet. Add. Mot. at 2. In addition, Petitioners fault the Special Master for applying a "novel and unique" requirement that Petitioners must "demonstrate that Aydien's 'current outcome is worse than what would normally occur' in the 'natural or expected course' of his preexisting condition." Pl. Add. Mot. at 2 (quoting *Santini* at *18).

D. The Government's Response.

The Government responds that Petitioners' "arguments are nothing more than an attempt to couch their disagreements with the [S]pecial [M]aster's factual findings as legal error in hopes of invoking a less deferential standard of review." Gov't Resp. at 9. Recent authority in Vaccine Act cases concerning SCN1A mutations (based largely on the evidence of Drs. Wiznitzer and Raymond) requires the court to uphold the findings of the Special Master as a matter of law. Gov't Resp. at 9−11 (citing *Stone/Hammitt v. Sec'y of Health & Human Servs.*, 676 F.3d 1373 (Fed. Cir. 2012); *Snyder/Harris v. Sec'y of Health & Human Servs.*, 553 F. App'x 994 (Fed. Cir. 2014)).

The Special Master in this case did not act arbitrarily and capriciously by not citing the two articles proffered by Petitioners. Gov't Resp. at 18–19. In fact, these articles should be afforded little weight, because Petitioners' expert did not discuss them, and Dr. Raymond did not consider them to be relevant. Gov't Resp. at 18−19.

The Government also contests Petitioners' challenge to the Special Master's application of the "severity requirement" of 42 U.S.C. § 300aa-11(c)(1)(D)(i) as not in accordance with law. Gov't Resp. at 11−17. To the contrary, the Special Master "correctly considered whether Aydien's initial seizure *resulted* in the required six months of residual effects, as the Act required." Gov't Resp. at 16 (emphasis added).

E. The Court's Resolution.

As a threshold matter, the Government argues that this Petition must be rejected out of hand, because the United States Court of Appeals for the Federal Circuit has affirmed other Special Masters' reliance on the opinions of Drs. Wiznitzer and Raymond that: a SCN1A mutation was the sole cause of other petitioners' Dravet's Syndrome; and the mutation was a "factor unrelated" to the DTaP vaccine. Gov't Resp. at 9−11 (citing *Stone*/*Hammitt*, 676 F.3d at 1384 ("In sum, because of Dr. Raymond's expert testimony and the considerable evidentiary support for his views in the record, we cannot conclude that the [S]pecial [M]aster's conclusion that the SCN1A gene mutation was solely responsible for [the plainitff's] SMEI was arbitrary or capricious."); *Snyder*, 553 F. App'x at 1002 ("[T]he Special Master concluded Drs. Wiznitzer's and Raymond's opinions 'merit consideration' . . . . This court does not discern error in this conclusion.")). The Government would have the court determine that the expert opinions of Drs. Wiznitzer and Raymond are dispositive in all cases where a child has a mutation of the SCN1A gene, without regard for factual differences in other cases or future scientific evidence. *See Rickett v. Sec'y of Health & Human Servs.*, 468 F. App'x 952, 959 (Fed. Cir. 2011) ("A [S]pecial [M]aster's acceptance of a theory in one case does not require him or her to accept the theory in subsequent cases involving similar facts or the same vaccine. A different evidentiary record, however, can lead to different outcomes. To decide otherwise would effectively require [S]pecial [M]asters to ignore the impact of ever-changing technological advances and medical breakthroughs that might discredit the plausibility of a formerly accepted theory.") (internal citations omitted). Therefore, the court declines the Government's invitation.

Moreover, in particular, Dr. Wiznitzer, who appears regularly for the Government in Vaccine Act cases, does not have any extensive academic qualifications, clinical training, or board certification in genetics or the causes of "the symptomatic mutation" of any gene, much less the SCN1A gene.[9] Moreover, during his thirty-eight-year career, Dr. Wiznitzer has seen or consulted on only "between six and 10" children with Dravet's Syndrome. 6/6/13 TR 343 (Wiznitzer). Therefore, the Special Master's decision to rely on Dr. Wiznitzer's medical opinion, in this case,

[9] In contrast, Dr. Raymond received a three-year fellowship at Massachusetts General Hospital in genetics and teratology, and his clinical work focused "predominantly on the interaction between neurology and genetics." 6/5/13 TR 221–23 (Raymond). In addition, Dr. Raymond is board-certified in clinical genetics and neurology. 6/5/13 TR 223 (Raymond).

is contrary to FED. R. EVID. 702[10] and arbitrary and capricious. *See* 42 U.S.C. § 300aa-12(e)(2)(B) (authorizing the United States Court of Federal Claims to set aside a Special Master's findings of fact or conclusions, if it determines they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law").

As for the merits, the United States Court of Appeals for the Federal Circuit has made clear that the Vaccine Act "relaxes proof of causation for injuries satisfying the Table in § 300aa-14, but does not relax proof of causation in fact for non-Table Injuries."[11] *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)).

Neither SMEI nor Dravet Syndrome is listed on the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-14. Therefore, "[w]here, as here, the claimed injury is not listed in the Vaccine Injury Table, a claimant may obtain compensation by showing that his injury was 'caused in fact' by the vaccine or vaccines he received." *Paluck*, 2015 WL 2403354 at *4. As such, Petitioners must demonstrate more than a "plausible" or "possible" causal link between the vaccination and the injury. *Moberly*, 592 F.3d at 1322 ("[T]he applicable level of proof is not certainty, but the traditional tort standard of 'preponderant evidence.'"). Specifically, to prove causation-in-fact, Petitioners must: "(1) provide a medical theory causally connecting the vaccination to the injury; (2) demonstrate a logical sequence of cause and effect showing that the vaccination was the reason

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[10] Rule 702 provides:

> A witness who is *qualified as an expert by knowledge, skill, experience, training, or education* may testify in the form of an opinion or otherwise if:
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> > (a) the expert's *scientific, technical, or other specialized knowledge* will help the trier of fact to understand the evidence or to determine a fact in issue;
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> > (b) the testimony is based on sufficient facts or data;
> >
> > (c) the testimony is the product of reliable principles and methods; and
> >
> > (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702 (emphases added).

[11] Petitioners, however, erroneously conflate the burden of proof imposed for off-Table injuries with the statutory presumptions for on-Table injuries. Indeed, Petitioners mistakenly rely on the prescribed periods of time for on-Table injuries in supporting their argument for this off-Table case. Pet. Mot at 10 ("The way 'significantly aggravated' and 'significant aggravation' are used in sections 11(c) and 14(a) of the Act and the specific and relatively brief time periods in the Vaccine Injury Table indicate that the term 'significant aggravation' in the Act denotes an acute event in which the first symptom or manifestation occurs over hours or days.").

for the injury; and (3) establish a proximate temporal relationship between the vaccination and the injury." *Paluck*, 2015 WL 2403354 at *4 (citing *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)).

If a petitioner demonstrates causation-in-fact by a preponderance of evidence, the burden of proof then shifts to the Government to establish that "there is . . . a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition." 42 U.S.C. § 300aa-13(a)(1)(B). The petitioner bears no burden to rule out possible alternative causes. *See De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) ("So long as the petitioner has satisfied all three prongs of the *Althen* test, she bears no burden to rule out possible alternative causes.").

In this case, "[a]ll experts agree that there is a causal relationship between the vaccinations and the initial seizure. More specifically, the DTaP vaccine prompted a fever and fever, in children with an SCN1A mutation, can prompt a seizure. The [Government's] experts conceded this point without dispute." *Santini* at *19. Therefore, the Special Master considered the determinative issue to be whether Aydien's second vaccination caused SMEI or Dravet Syndrome.[12]

The Special Master fairly characterized the testimony of Petitioners' expert, Dr. Corbier, as follows:

> To explain *how a vaccine could change the effect of an SCN1A mutation* Dr. Corbier presented three overlapping theories in his testimony. A first idea is that people with an SCN1A mutation are vulnerable or susceptible to developing an adverse reaction to the DTaP vaccine. A second theory is that vaccines cause Dravet syndrome to manifest earlier by bringing about the seizures before they would have occurred otherwise. . . . A third concept from Dr. Corbier is that the vaccines cause a more prolonged seizure and the prolonged seizure inflicts additional damage.

Santini at *11 (internal citations omitted) (emphasis added).

The Special Master concluded that "Dr. Corbier was not persuasive in his opinion that vaccinations affected Aydien's outcome. . . . Consequently, Petitioners have failed to establish the first prong of *Althen*[.]" *Id.* at *18.

[12] If the Special Master considered the initial seizures alone, Petitioners would not be entitled to compensation, because Aydien did not suffer residual effects of the first seizures within six months after his first vaccination. *See* 42 U.S.C. § 300aa-11(c)(1)(D)(i) ("A petition for compensation under the Program for a vaccine-related injury or death shall contain . . . an affidavit, and supporting documentation, demonstrating that the person who suffered such injury . . . suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine[.]"); *see also Santini* at *19 (within four days of Aydien's November 7, 2003 seizures, he returned to the hospital in "good condition").

Persuasiveness was not the problem with Dr. Corbier's testimony. Like Dr. Wiznitzer, Dr. Corbier did not have the required credentials to qualify as an expert in genetics or the causes of gene mutation. More importantly, Dr. Corbier posited no medical theory linking Aydien's vaccination to Dravet's Syndrome. 6/5/13 TR at 78–89; *see W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (holding that such medical theories do not require "scientific certainty" or "general acceptance in the scientific or medical communities"). Therefore, since Petitioners failed to meet their burden of proof, Dr. Raymond's opinion that "Aydien's mutation is the primary and . . . sole cause of his developing Dravet's Syndrome" was extraneous. 6/5/13 TR at 227. Moreover, it was beside the point, as the relevant inquiry was overlooked by all of the experts, lawyers, and Special Master in this case.

The National Institutes of Health defines a gene mutation as a "permanent alteration in the DNA sequence[.]" *See* NAT'L INSTS. OF HEALTH, *Genetics Home Reference: What Is A Gene Mutation And How Do Mutations Occur?*, http://ghr.nlm.nih.gov/handbook/mutationsand disorders/genemutation ("NIH") (last visited May 26, 2015). The record reflects that Aydien's mutation was *de novo*. Pet. Ex. 29, at 183 (11/25/08 Athena Diagnostics, Inc. Service Report). *De novo* mutations may occur during embryonic development or after birth. *See* NIH. The Special Master found that "[w]hen he was born, [Aydien] already possessed the genetic mutation." *Santani* at *5 (citing 6/5/13 TR 73, 95 (Corbier)). On page 73, however, the testimony of Dr. Corbier says nothing about *when* the gene mutation occurred. 6/5/13 TR at 73 (Corbier). On page 95, Dr. Corbier was asked by the Government's counsel on cross-examination: "Do you agree that [Aydien's] SCN1A mutation was a pre-existing condition, meaning that he had it since birth?" Dr. Corbier's answer was: "Yes, that's my belief, Yes." 6/5/13 TR at 95 (Corbier). Dr. Corbier was not asked on what that belief was based, either on cross-examination or redirect. In any event, Dr. Corbier did not have the expert credentials to proffer an expert medical opinion on this issue. Therefore, the Special Master had no basis to conclude that Aydien was born with a mutation of his SCN1A gene, and doing so was arbitrary and capricious.

When a *de novo* mutation occurs is significant, because a mutation that takes place after birth "can be *caused by environmental factors* such as ultraviolet radiation from the sun, or can occur if a mistake is made as the DNA copies itself during cell division." NIH (emphasis added); *see also* NAT'L INSTS. OF HEALTH, *Genetics Home Reference: Mutation*, http://ghr.nlm.nih.gov/ glossary=mutation (mutations also can result from "exposure to ionizing radiation, *exposure to chemicals called mutagens, or infection by viruses.*") (last visited May 26, 2015). Therefore, the relevant inquiry in this case was whether Aydien's second vaccine caused the *de novo* mutation of his SCNIA gene, not whether the vaccine caused the symptoms of Dravet's Syndrome.

Dr. Raymond testified that seventy-five to eighty percent of children with Dravet's Syndrome have SCN1A genetic mutations. 6/5/13 TR at 243 (Raymond). For those children whose SCN1A mutations occur before birth, childhood vaccinations will have no effect on whether or the degree to which they experience developmental delays. For those children who develop *de novo* mutations after birth, however, the role, if any, of childhood vaccines in causing the mutation is important to explore in future cases, particularly in light of the exponential growth of knowledge about human genetics.

IV. CONCLUSION.

For the reasons discussed herein, since Petitioners' failed to meet their burden of proof, the court is compelled to affirm the Special Master's December 15, 2014 Decision.

IT IS SO ORDERED.

/s/ Susan G. Braden__
SUSAN G. BRADEN
Judge